REMARKS

Reconsideration of the above-identified application is respectfully requested. Claims 30-32 are currently pending and under consideration. By the present amendment, claim 31 is canceled, and claims 30 and 32 are amended to more specifically recite certain aspects of the invention. Support for these amendments can be found throughout the instant specification, and no new matter is introduced by the subject amendments.

Objection to the Claims and Abstract

Claim 32 stands under objection for reciting, "the 3' end of SEQ ID NO:2," which is a polypeptide. To expedite prosecution, claim 32 has been amended to replace the objected to language with the phrase, "the carboxyl end of SEQ ID NO:2," as suggested by the Examiner.

The abstract stands under objection for having the title, "Abstract of the Invention." The title of the abstract has been amended to recite, "Abstract of the Disclosure," as suggested by the Examiner.

In light of these amendments, it is submitted that these bases of objection have been overcome, and Applicants respectfully request that they be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph, New Matter

Claims 31 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the specification does not contain a written description of the presently claimed invention. More specifically, the Examiner alleges that the limitation of claim 31 related to a nucleotide sequence that has greater than 85% nucleotide identity to the sequence of SEQ ID NO:1 has no clear support in the application as originally filed. In addition, the Examiner alleges that the limitation of claim 32 related to a fragment of no greater than 95 contiguous amino acids of the 3' end of SEQ ID NO:2 and the limitation of claim 32 related to at least one amino acid differing from SEQ ID NO:3 have no clear support in the application as originally filed.

Applicants respectfully traverse these bases of rejection and submit that the subject matter of the present claims does not constitute new matter. Nonetheless, without acquiescence to this basis of rejection, claim 31 has been canceled. In addition, also without

acquiescence to this basis of rejection, claim 32 has been amended to specifically recite a fragment consisting of the 95 carboxyl amino acids of SEQ ID NO:2. Support for this amendment is provided, *e.g.*, on page 27, lines 14-16, as acknowledged by the Examiner in the instant Office Action.

In light of these amendments and remarks, Applicants submit that the claims do not encompass new matter and respectfully request that these bases of rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claim 31 stands rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the instant specification does not contain a written description of the invention in sufficient detail that one skilled in the art can reasonably conclude that Applicants had possession of the invention at the time of filing the instant application. Specifically, the Examiner asserts that the specification does not provide adequate written description support for polypeptides encoded by nucleotide sequences having greater than 85% identity with SEQ ID NO:1, since the specification allegedly does not provide the complete structure of a representative number of such polypeptides or describe sufficient structural features common to the members of the genus.

Without acquiescence to this basis of rejection, claim 31 has been canceled. Accordingly, Applicants respectfully request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claim 31 stands rejected under 35 U.S.C. § 112, first paragraph, on the basis that the instant specification is not enabling for an antibody that binds an isolated human Bad polypeptide encoded by a nucleotide sequence that has greater than 85% nucleotide identity to SEQ ID NO:1.

Without acquiescence to this basis of rejection, claim 31 has been canceled. Accordingly, Applicants respectfully request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(e)

Claims 30-32 stand rejected under 35 U.S.C. § 102(e), for allegedly being anticipated by U.S. Patent No. 5,622,852 (the '852 patent). More specifically, the Examiner asserts that the '852 patent teaches a polyclonal antibody to a mouse Bad polypeptide. The Examiner concludes that such antibodies would specifically bind to the polypeptide of SEQ ID NO:2, since the mouse Bad polypeptide is 75% similar to SEQ ID NO:2, from amino acid residues 1 to 168. The Examiner's conclusion rests on the assertion that it is well known in the art that different components or subsets of a polyclonal antibody would bind to multiples sites of a protein and that the mouse Bad polypeptide includes several stretches of contiguous amino acids that are the same as those in SEQ ID NO:2, which would share common epitopes of subsets of the polyclonal antibody against the mouse Bad polypeptide.

Applicants respectfully traverse this basis of rejection and submit that the teachings of the '852 patent do not anticipate the instant claims. As an initial matter, Applicants note that claim 31 has been canceled, and claims 30 and 32 have been amended to recite monoclonal antibodies. Support for this amendment is provided in the instant application, *e.g.*, on page 15, line 27, to page 16, line 2.

Applicants submit that the '852 patent fails to teach the claimed monoclonal antibodies, which specifically bind to an isolated human Bad polypeptide of SEQ ID NO:2 (claim 30) or a fragment thereof consisting of the carboxy terminal 95 amino acid residues of the human Bad polypeptide (claim 32). Rather, as noted by the Examiner, the '852 patent only describes the generation of polyclonal sera against the mouse Bad polypeptide (*see, e.g.*, column 53, lines 7-9). Furthermore, the '852 patent fails to disclose either the nucleotide or polypeptide sequence of human Bad, and, therefore, does not provide for the generation of monoclonal antibodies that specifically bind human Bad polypeptide sequences. As further noted by the Examiner, the human and mouse Bad polypeptides are only approximately 75% identical, and the skilled artisan would appreciate that this is simply not a high enough similarity to ensure that any particular monoclonal antibody generated against mouse Bad would inherently bind to human Bad, given the unpredictable nature of protein structure.

As explicitly stated by the Federal Circuit, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency

of that result or characteristic." *In re Rijckaert,* 9 F.3d 1531, 1534 (Fed. Cir. 1993); *In re Oelrich,* 666 F.2d 578, 581-82 (CCPA 1981). Rather, "to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robinson,* 169 F.3d 743, 745 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Applicants submit that while it might be possible that a monoclonal antibody generated against a mouse Bad polypeptide would cross-react with a human Bad polypeptide, the Examiner has failed to provide evidence or substantiated reasoning that any of the antibodies described in the '852 patent would necessarily bind to a human Bad polypeptide, as required to establish a *prima facie* case of anticipation based upon a theory of inherency.

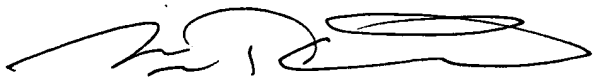
Accordingly, Applicants submit that the '852 patent fails to anticipate the presently claimed invention drawn to monoclonal antibodies that specifically bind isolated human Bad polypeptides. In light of these amendments and remarks, Applicants respectfully request that this basis of rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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